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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,426	04/27/2006	Toshio Matsumoto	P29832	4734
7055 7590 03/13/2009 GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191				
EXAMINER VO, HAI				
ART UNIT		PAPER NUMBER		
1794				
NOTIFICATION DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/577,426

Applicant(s)

MATSUMOTO ET AL.

Examiner

Hai Vo

Art Unit

1794

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1, 2, 4-12 and 14-16 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 and 14 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-8, 15 and 16 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

1. The art rejections have been withdrawn in view of the present amendment and response (see pages 7 and 8 of the amendment filed 12/01/2008). However, upon further consideration, new ground of rejection is made in view of newly discovered reference to Troczynski et al (US 6,426,114), Ahn (US 2005/0031704), and Ito et al (US 2005/0049715).
2. The 112 claim rejections have been withdrawn in view of the present arguments.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1, 2, 4-8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troczynski et al (US 6,426,114) in view of Ito et al (US 2005/0049715). Note that a dispersant is completely removed from the three-dimensional nanotunnel layers by heat treatment, any limitations associated with the dispersant in the final product of the claimed ceramic body are considered irrelevant to the claims. Troczynski discloses an implantable article comprising a porous substrate and a ceramic coating formed in the fine pores inside the substrate (example, column 7, lines 1-8). The porous substrate has pores with an average pore size of 50 to 200 microns and a porosity of 35 to 40% (column 7, lines 5-8). The coating is made from a porous calcium phosphate material

which allows circulation of the physiological fluid throughout the coating structure (column 5, lines 33-36). This at least indicates that the ceramic coating is a three-dimensional structure having pores which are interconnecting with themselves so as to allow circulation of the physiological fluid throughout the coating structure. The pores are connected and ranging from 0.3 to 1 micron within the claimed range (column 6, lines 55-60). The coating is uniform within the fine pores of the substrate (column 7, lines 5-10). Likewise, the coating is formed on 100% of the wall surface of the fine pores. The coating has a thickness of 1 to 5 microns (column 7, lines 53-55). The ceramic coating has a Ca/P ratio of 1.666 (column 4, lines 60-64). Troczynski does not specifically disclose the substrate is a porous calcium phosphate substrate. Ito, however, teaches an implant comprising a porous substrate of calcium phosphate having a Ca/P molar ratio of 1.67 (paragraph 32), a porosity of 50% or more, the pores with pore size of 70 microns or more. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the porous calcium phosphate for the substrate motivated by the desire to facilitate osteogenesis activity while maintaining the strength of the implant.

Troczynski does not specifically disclose the steps of making a porous calcium phosphate ceramic body. However, it is a product-by-process limitation not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Troczynski as modified by Ito is identical to or only

slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with Troczynski/Ito.

5. Claims 1, 2, 4-8, 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Troczynski et al (US 6,426,114) in view of Ito et al (US 2005/0049715) and Ahn (US 2005/0031704). Troczynski discloses an implantable article comprising a porous substrate and a ceramic coating formed in the fine pores inside the substrate (example, column 7, lines 1-8). The porous substrate has pores with an average pore size of 50 to 200 microns and a porosity of 35 to 40% (column 7, lines 5-8). The porous coating is made from a

calcium phosphate coating which allows circulation of the physiological fluid throughout the coating structure (column 5, lines 33-36). This at least indicates that the ceramic coating is a three-dimensional structure having pores which are interconnecting with themselves so as to allow circulation of the physiological fluid throughout the coating structure. The pores are connected and ranging from 0.3 to 1 micron within the claimed range (column 6, lines 55-60). The coating is uniform within the fine pores of the substrate (column 7, lines 5-10). Likewise, the coating is formed on 100% of the wall surface of the fine pores. The coating has a thickness of 1 to 5 microns (column 7, lines 53-55). The ceramic coating has a Ca/P ratio of 1.666 (column 4, lines 60-64). Troczynski does not specifically disclose the substrate is a porous calcium phosphate substrate. Ito, however, teaches an implant comprising a porous substrate of calcium phosphate having a Ca/P molar ratio of 1.67 (paragraph 32), a porosity of 50% or more, the pores with pore size of 70 microns or more. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to substitute the porous calcium phosphate for the substrate motivated by the desire to facilitate osteogenesis activity while maintaining the strength of the implant.

Troczynski does not specifically disclose the coating comprising a non-ionic surfactant. Ahn, however, teaches a calcium phosphate composition that serves as a coating for prosthetic implants (abstract). The coating is porous and includes a non-ionic surfactant as an organic additive (paragraph 63). Therefore,

it would have been obvious to one having ordinary skill in the art at the time the invention was made to add a nonionic surfactant into the ceramic coating of Troczynski because such is an intended use of the material and Ahn provides necessary details to practice the invention of Troczynski.

Troczynski does not specifically disclose the steps of making a porous calcium phosphate ceramic body. However, it is a product-by-process limitation not as yet shown to produce a patentably distinct article. It is the examiner's position that the article of Troczynski as modified by Ito and Ahn is identical to or only slightly different than the claimed article prepared by the method of the claim, because both articles are formed from the same materials, having structural similarity. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or an obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289,291 (Fed. Cir. 1983). It is noted that if the applicant intends to rely on Examples in the specification or in a submitted Declaration to show non-obviousness, the applicant should clearly state how the Examples of the present

invention are commensurate in scope with the claims and how the Comparative Examples are commensurate in scope with Troczynski/Ito/Ahn.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax

phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Hai Vo/
Primary Examiner, Art Unit 1794